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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/367,712	08/18/1999	JOHN SEFTON	17224(AP)	4667

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EXAMINER

BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 06/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.



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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 09/367,712  
Filing Date: August 18, 1999  
Appellant(s): SEFTON, JOHN

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Brent A. Johnson  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed March 26, 2004.

**(1) *Real Party in Interest***

A statement identifying the real party in interest is contained in the brief.

**(2) *Related Appeals and Interferences***

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

**(3) *Status of Claims***

The statement of the status of the claims contained in the brief is correct.

**(4) *Status of Amendments After Final***

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) *Summary of Invention***

The summary of invention contained in the brief is correct.

**(6) *Issues***

The appellant's statement of the issues in the brief is correct.

**(7) Grouping of Claims**

Appellant's brief includes a statement that claims 1-3 and 6-8, 10 and 11 do not stand or fall together.

**(8) Claims Appealed**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(9) Prior Art of Record**

4,775,529	SEQUEIRA et al.	10-1988
5,236,906	YAMAMOTO	08-1993
5,650,279	NAGPAL et al.	07-1997
5,874,074	SMITH	02-1999

**(10) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-3, 6-8, 10 and 11 are rejected under 35 U.S.C. 103(a). This rejection is set forth in a Board Decision mailed on September 24, 2003.

**(11) Response to Argument**

Applicant argues the specification of the present application contains evidence of unexpected results which are sufficient to overcome the obviousness rejection for the scope of the claims as currently amended. Applicant also argues the Examiner's

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response to the evidence is incorrect. Applicant's argument was not persuasive for the following reasons.

The evidence of record referred to by applicant was before the Board of Appeals when the previous Decision was made. The Board did not find applicant's evidence of unexpected results sufficient to overcome the prima facie showing of obviousness of record. However, Applicant argues that said evidence of record is sufficient to overcome the prima facie case of obviousness over the presently claimed invention.

In the previous Decision by the Board, it was noted that "it is impossible to conclude from Table II that the incidence of adverse events was consistently lower in patients treated with mid- or high-potency corticosteroid in combination with tazarotene as compared with patients treated with low-potency corticosteroid in combination with tazarotene, or tazarotene alone." The Board noted that patients suffered greater burning when treated with a combination of tazarotene and high-potency corticosteroid (see page 6 of the Board's Decision). The evidence presented in Example 2 was also not persuasive because it was unsupported by data. The examiner maintains as previously stated by the Board that the evidence of record is not sufficient to overcome the prima facie showing of obviousness of record of the presently claimed invention.

For additional support, Applicant refers to a reference by Gollnick (British Journal of Dermatology 1999; 140 (Suppl. 54): 18-23) and states that said reference supports the assertion of unexpected results originally made in the present application. The examiner notes that the incidence of treatment-related adverse events for tazarotene plus mid- or high-potency corticosteroid is almost identical, i.e., 32% and 31%

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respectively and, thus, cannot support any assertion of unexpected results as suggested by applicant.

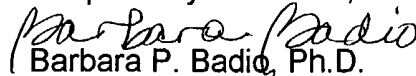
In response to the Examiner's argument that the comparison was improper because Applicant had utilized different amounts of corticosteroid in each case, Applicant argues that the comparison is properly made using potency. The examiner is aware that drugs may have different potencies. However, applicant's specification indicates the effective dose of corticosteroid is within the "ranges from about 0.001% to about 1% of the pharmaceutical preparation" (see page 5, lines 15-18 of the present specification). Thus, the examiner sees no reason why applicant could not utilize similar amounts of corticosteroids in each case. In addition, the utilization of low-, mid- and high-potency would imply that at identical concentrations, the efficacy of corticosteroids would be as recited and, thus, the skilled artisan would expect the high-potency corticosteroid to be most effective when used at similar concentration as the others. However, in the comparison applicant utilizes twice the amount of high-potency corticosteroid as mid-potency corticosteroid. The examiner's position is that said comparison is not a true side-by-side comparison.

In summary, the evidence set forth in the present specification was before the Board previously. The Board did not find said evidence sufficient to overcome the prima facie case presented. The examiner's position is that said evidence it still not sufficient to overcome the prima facie case of obviousness in regards to the presently claimed invention.

For the above reasons, it is believed that the rejections should be sustained.

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Respectfully submitted,

  
Barbara P. Badio, Ph.D.

Primary Examiner

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BB

June 9, 2004

  
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